

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
1 May 2003 (01.05.2003)

PCT

(10) International Publication Number
WO 03/035158 A2

- (51) International Patent Classification⁷: **A61M 25/00** (74) Agents: **CROMPTON, David, M.** et al.; Crompton, Seager & Tufte LLC, Suite 895, 331 Second Avenue South, Minneapolis, MN 55401-2246 (US).
- (21) International Application Number: **PCT/US02/28995**
- (22) International Filing Date:
12 September 2002 (12.09.2002) (81) Designated States (*national*): CA, JP.
- (25) Filing Language: English (84) Designated States (*regional*): European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR).
- (26) Publication Language: English
- (30) Priority Data:
10/032,962 24 October 2001 (24.10.2001) US Published:
— without international search report and to be republished upon receipt of that report
- (71) Applicant: **SCIMED LIFE SYSTEMS, INC.** [US/US];
One SciMed Place, Maple Grove, MN 55311 (US).
- (72) Inventor: **HEIDNER, Matthew**; 9159 Rosewood Lane
North, Maple Grove, MN 55369 (US).
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*



WO 03/035158 A2

(54) Title: **DISTAL BALLOON WAIST MATERIAL RELIEF AND METHOD OF MANUFACTURE**

(57) Abstract: A balloon catheter having an improved balloon waist design in which material is removed prior to thermal processing. In one embodiment, a series of patterned voids are formed in the balloon waist to reduce the amount of polymeric material and to better control flowing polymeric material during thermal processing.

DISTAL BALLOON WAIST MATERIAL RELIEF AND METHOD OF MANUFACTURE

Technical Field

5 The present invention generally relates to the field of medical devices. More specifically, the present invention relates to intravascular balloon catheters.

Background of the Invention

Intravascular diseases are commonly treated by relatively non-invasive
10 techniques such as percutaneous transluminal angioplasty (PTA) and percutaneous transluminal coronary angioplasty (PTCA). These therapeutic techniques are well known in the art and typically involve the use of a balloon catheter with a guidewire, possibly in combination with other intravascular devices such as stents. A typical balloon catheter has an elongate shaft with a balloon attached proximate its distal end
15 and a manifold attached to its proximal end. In use, the balloon catheter is advanced over the guidewire such that the balloon is positioned adjacent a restriction in a diseased vessel. The balloon is then inflated and the restriction in the vessel is opened.

Several characteristics that are important in intravascular balloon catheters
20 include pushability, trackability and crossability. Pushability refers to the ability to transmit force from the proximal end of the catheter to the distal end of the catheter. Trackability refers to the ability to navigate tortuous vasculature. Crossability refers to the ability to cross narrow restrictions in the vasculature, such as stenosed vessels. There is an ongoing effort to provide improved balloon catheters in terms of each of
25 these characteristics.

Summary of the Invention

The present invention contributes to this ongoing effort by providing, for example, an improved balloon catheter that has a reduced amount of material in the
30 balloon waist in order to reduce profile and increase flexibility. The reduction in profile and the increase in flexibility enhances the trackability and crossability of the balloon catheter.

Brief Description of the Drawings

Figure 1 is a plan view of a balloon dilation catheter in accordance with an embodiment of the present invention;

Figure 2 is a partial cross-sectional view of a distal tip design of the catheter of
5 Figure 1;

Figure 3 is a cross-sectional view of a distal tip design of the present invention;

Figure 4 is a side fragmented view of one distal balloon waist embodiment of the present invention;

10 Figure 5 is a side fragmented view of another distal balloon waist embodiment of the present invention;

Figure 6 is a side fragmented view of another distal balloon waist embodiment of the present invention; and

15 Figure 7 is a side fragmented view of yet another distal balloon waist embodiment of the present invention.

Detailed Description of the Preferred Embodiments

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same.

20 The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

Referring now to the drawings, Figure 1 is a plan view of an over-the-wire (OTW) balloon catheter 10, which is representative of one type of catheter that may incorporate the present invention. Other intravascular balloon catheters are
25 additionally suitable without deviating from the spirit and scope of the present invention. For example, other intravascular balloon catheters suitable for incorporating the present invention include fixed-wire (FW) catheters and single-operator-exchange (SOE) catheters.

The balloon catheter 10 includes a shaft assembly 12 and a balloon assembly
30 14 connected proximate the distal end of shaft assembly 12. A conventional OTW-type manifold assembly 16 may be connected to the proximal end of the shaft assembly 12.

The shaft assembly 12 may have conventional dimensions and may be made of conventional materials suitable for intravascular navigation as in, for example, conventional angioplasty procedures. The shaft assembly 12 may be a dual lumen design or a coaxial design as shown. In a coaxial design, the shaft assembly 12 includes an inner tubular member 22 and an outer tubular member 26. The inner tubular member 22 defines a guidewire lumen, and the outer tubular member 26 is coaxially disposed about the inner tubular member 22 to define an annular inflation lumen therebetween.

At the distal end of the shaft assembly 12 is a balloon assembly 14. The balloon assembly 14 includes an expandable balloon portion 28 having a proximal balloon waist 30 and a distal balloon waist 32. The proximal balloon waist 30 connects the balloon assembly 14 to the outer tubular member 26 near its distal end by means of an adhesive and/or a thermal bond. The distal balloon waist 32, as shown best in Figure 2, similarly connects the balloon assembly 14 to the inner tubular member 22 near its distal end by means of an adhesive bond and/or a thermal bond. This particular balloon assembly 14 arrangement allows the expandable balloon portion 28 to be in fluid communication with the annular inflation lumen defined between the outer tubular member 26 and the inner tubular member 22.

Figure 2 shows a partial cross-sectional view of the distal tip section of the catheter 10 shown in Figure 1. The distal tip section includes the expandable balloon 28, the distal cone 34, the distal balloon waist 32 and the distal end of the inner tubular member 22. The cone 34 of the balloon assembly tapers inwardly toward the distal balloon waist 32. Generally, the thickness of the material forming the distal balloon waist 32 is similar in thickness as the material forming the distal end of the cone 34, absent further processing.

As described in detail above, the distal balloon waist 32 is connected to the inner tubular member 22 near its distal end by means of an adhesive bond and/or a thermal bond. In certain embodiments, the distal balloon waist 32 is only connected to the inner tubular member 22 which extends beyond the distal balloon waist 32. In alternative embodiments, the distal balloon waist 32 is connected to the inner tubular member 22 and a distal tip member 36. In these embodiments, the separate distal tip segment 36 extends distal of the inner tubular member 22 and the distal balloon waist 32. The separate distal tip segment 36 may comprise a soft polymeric material that

allows the catheter 10 to navigate and traverse the tortuous pathways of a patient's vasculature in an atraumatic manner. In embodiments possessing a separate distal tip segment 36, both the inner tubular member 22 and the separate distal tip segment 36 may be connected to the distal balloon waist 32.

5 Materials suitable for the separate distal tip segment 36 include, by way of example, not limitation, a polyethylene, polyamide, or block copolymer such as PEBAX having a durometer between about 50D and 70D. In some embodiments, the distal tip 36 may comprise a polymeric material having a durometer of about 63D which is heat welded or bonded to the distal end of the inner tubular member 22. In
10 alternative embodiments, the distal 1/2 to 1 mm of the distal tip 36 may be made of a different material than that of the remaining portion of the distal tip 36. In particular, the distal 1/2 to 1 mm may be made from a material that is more durable relative to the remaining softer distal tip material. The more durable material resists deforming or tearing when in use, such as in tracking the patient's tortuous anatomy. For
15 example, the distal 1/2 mm to 1 mm may be manufactured from Marlex high-density polyethylene having a hardness of approximately 63D durometer. This distal tip material may improve the integrity of the tip region at its distal-most end.

In order to provide a smooth transition from the distal balloon waist 32 to the inner tubular member 22, or alternatively to the distal tip section 36, a taper 38 may
20 be formed. There are numerous methods for forming the taper 38 on the distal balloon waist 32.

In one procedure, a grinding wheel is utilized to ablate the distal balloon waist 32 into a tapered end 38. The ablating wheel may be aligned so as to remove only the excess polymeric material, while not ablating any sections of the inner tubular
25 member 22 or separate distal tip segment 36. Because this procedure may be dependent on operator skill, it may be desirable that the taper 38 only encompass a small portion of the distal balloon waist 32, as depicted in Figure 2, to prevent improper ablation of either the distal balloon waist 32 or the inner tubular member 22.

In another embodiment, a backfilling procedure may be utilized to obtain a
30 tapered profile 38 for the distal tip section. Similar to the ablation procedure described above, the creation of a proper taper 38 utilizing a backfilling material may be dependent on operator skill. In this procedure, an operator first applies an appropriate amount of material between the distal end of the balloon waist 32 and the

distal tip section. The operator may then sculpt the backfill material to provide the desired transition between the distal balloon waist 32 and the inner tubular member 22. A taper 38 formed from such a backfilling procedure looks similar to the distal tip section depicted in Figure 2.

5 In yet another embodiment, laser welding may be used to direct a focused beam of energy upon the distal end of the distal balloon waist 32. The laser eventually causes the distal end of the distal balloon waist 32 to melt and flow. The flowing polymeric material is then formed to produce a tapered end 38 similar to that depicted in Figure 2. Flowing and forming the polymeric material to achieve a
10 uniform and full length taper may be difficult to control and may lead to undesirable polymeric aberrations on the balloon assembly 14.

In the grinding procedure described above, only the distal end of the distal balloon waist 32 is typically tapered. As a result, a considerable amount of the material forming the distal balloon waist 32 may remain. In the backfilling
15 procedure, more material is added upon that region of the catheter assembly. In the laser welding procedure, no material need be removed from the balloon waist 32, the material is simply allowed to re-flow and formed into a taper. Since flexibility in the distal tip section is dependent upon the quantity of polymeric material in the region, a method that removes excess material from the distal balloon waist 32 would provide a
20 reduction in profile and an increase in flexibility and, therefore, would improve the crossability and trackability of the catheter 10 as a whole.

The trackability of a particular catheter design may be analyzed in terms of the trackability of the distal portion of the catheter 10. The distal portion is the section of the catheter 10 that must track the guidewire through the small tortuous vessels of a
25 patient's vasculature. The size of the distal tip, the flexibility of the distal tip, and the lumen diameter all influence the trackability of the catheter 10. Imparting more flexibility to the distal portion of the catheter 10, in particular, has been found to improve trackability. Increasing the flexibility within the distal tip also improves handling and navigation over a guidewire.

30 To maximize crossability, the distal tip may incorporate a narrow profile that includes a smooth transition from the distal tip region through the balloon assembly 14. A narrow profile enables the catheter 10 to easily pass through tight restrictions.

Moreover, a smooth transition within the balloon assembly 14 reduces the occurrence of a portion of the catheter 10 becoming entangled within a deployed stent.

In a preferred procedure, the distal balloon waist 32 may be modified prior to its adherence to the catheter shaft 12. In particular, material is removed from the distal balloon waist 32 subsequent to blow molding the balloon 14 and prior to bonding the distal waist 32 to the inner tubular member 22. Material removal causes a decrease in material volume per unit length of the distal balloon waist 32 which, in turn, causes a reduction in profile of the distal waist 32 subsequent to thermal reformation. The material volume per unit length may decrease distally to impart a distally extending taper.

The material removed may be of a variety of shapes and patterns as described hereinafter. For example, the distal balloon waist 32 may have sections of material (voids) removed in predetermined patterns chosen to optimize the melt and flow phenomenon caused by thermal reformation (e.g., thermal bonding). The thermal reformation or bonding procedure melts the polymeric material of the distal balloon waist 32 and the patterned voids formed into the distal balloon waist 32 direct the flowing polymeric material and provide a place for the flowing polymeric material to pool. The pooled polymeric material is then allowed to solidify creating a uniform taper 40 along the entire length of the distal balloon waist 32, as depicted in Figure 3. The thermal bonding process also firmly adheres the distal balloon waist 32 to the inner tubular member 22. Thus, two or three procedures (reformation, bonding and tapering of the distal balloon waist) may be completed in a single manufacturing step.

Although the patterned voids have only been described in conjunction with the distal balloon waist 32, they may additionally or alternatively be incorporated into other polymeric surfaces on a catheter assembly. For example, the patterned voids may be incorporated into the proximal balloon waist 30. Reducing the material mass between the proximal end of the balloon waist 30 and the outer tubular member 26 increases flexibility of the balloon assembly region 14. This added flexibility eases navigation and increases the trackability of the catheter 10 as a whole.

The patterned voids are also particularly useful in forming lap joints between two compatible catheter segments. A lap joint generally forms a continuous connection between a first segment and a second segment of a catheter shaft. By definition, however, the profile of a lap joint is not contiguous between the two

segments. One segment is displaced over the second segment, forming a portion of catheter assembly having properties of both the first and second segments. In order to reduce the catheter shaft's profile, however, it is desirable to minimize and smooth the transition between the two segments of the lap joint. Providing the overlapping
5 segment of a lap joint with the patterned voids of the present invention allows for reduced variance in the catheter's profile, while providing the necessary structural integrity to insure connection of the two segments.

Figures 4-7 show embodiments incorporating various patterned void designs of the present invention. By way of example, not limitation, the patterned void
10 designs are shown incorporated into the material forming the distal balloon waist 32 of the catheter 10 of Figure 1. Generally to all of the following embodiments, removal of more material from the distal end of the distal balloon waist 32 than from the proximal end of the distal balloon waist 32 provides a taper 40 as shown. As a
15 result, often the concentration of the patterned voids is greater toward the distal end of the distal balloon waist 32 in order to provide the necessary tapering effect 40. Alternatively, larger patterned voids may be positioned toward the distal end of the distal balloon waist 32, while smaller voids are positioned at the proximal end of the distal balloon waist 32.

Referring now to the specific patterned void design examples, Figure 4 shows
20 a fragmented view of one distal balloon waist 32 embodiment having balloon waist material removed in a pattern that forms a plurality of wedges 42 in the distal balloon waist 32. The plurality of wedges 42 may be evenly spaced along the entire circumference of the distal balloon waist 32. The apexes 44 of each individual wedge
42 may be positioned toward the proximal end of the distal balloon waist 32. From
25 these apexes, material is removed as the wedge 42 fans outwardly toward the distal end of the distal balloon waist 32.

In certain embodiments, the wedges 42 may extend distally through the end of the distal balloon waist 32, as depicted specifically in Figure 4. In an alternative
embodiment, the wedges 42 stop fanning at a location proximal to the distal end of the
30 distal balloon waist 32. This embodiment forms a series of triangular shaped voids (not shown) in the distal balloon waist 32. In yet another embodiment, the direction of the wedges 42 may be reversed from the direction depicted in Figure 4. In this embodiment, the apex 44 of the wedge 42 is positioned at the distal end of the distal

balloon waist 32 with the wedge 42 fanning outwardly proximally. The direction of the wedge 42 may be dependent on the particular method of thermal bonding utilized.

The size of the wedges 42 formed may be dependent on the particular thermal bonding process utilized. In certain embodiments, a plurality of wedges 42 having the same dimensions are cut into the distal balloon waist 32 material. In an alternative
5 embodiment, the size of the wedges 42 is staggered. The staggered wedges 42 may have varying heights, widths, or both. Similarly, some wedges 42 may extend through the distal end of the distal balloon waist 32 while others may stop fanning at a location proximal to the distal end. Finally, a series of the wedges 42 may extend in
10 one direction, while another set of wedges 42 may extend in the opposite direction.

In some embodiments, the wedges 42 formed are cut in a manner that entirely removes all material within the confines of the wedge-shaped form. In alternative embodiments, only a portion of the material is removed within the confines of the wedge-shaped form thereby forming a void that reduces the wall thickness of balloon
15 waist 32 within the wedge-shaped form.

Figure 5 shows a fragmented view of another distal balloon waist 32 embodiment having balloon waist material removed in a plurality of circular formations 50. Although the circular formations 50 may be perfectly symmetrical, in alternative embodiments, the circular formations 50 may be oblong or a mix of both
20 formations. In general, the plurality of circular formations 50 may be spaced along the entire circumference of the distal balloon waist 32. In some embodiments, the circular formations 50 are evenly spaced, whereas in alternative embodiments, the spacing is arranged in order to direct the flow of melted polymeric material into a uniform taper 40.

Figure 5 illustrates how the concentration of circular formations 50 may increase toward the distal end of the distal balloon waist 32 to form the taper 40. A first series 52 of circular formations 50 are shown at the proximal most end being spaced a considerable amount apart from one another. The second series 54 of circular formations 50 are closer together and are more numerous than the first series
25 52 of circular formations 54. The third series 56 of circular formations 50 are positioned at the distal-most end of the distal balloon waist. This third series 56 of circular formations 50 is the most numerous and closely spaced of the entire set.
30

Similar to the previous embodiment depicted in Figure 4, the circular

formations 50 may be cut in a manner that entirely removes all material within the confines of the circular form. In an alternative embodiment, only a portion of the material is removed thereby forming a void that reduces the wall thickness of balloon waist 32 within the confines of the circular form.

5 Figure 6 shows a fragmented view of another distal balloon waist 32 embodiment having balloon waist material removed in a plurality of oblong rectangular formations 60. The oblong rectangular formations 60 illustrate how a series of formations may overlap or interweave with another series of formations in order to create an area of increased material removal. In this example, two distinct
10 series of oblong rectangular formations 60 are shown. The boundary of the first series 62 of oblong rectangular formations 60 is entirely defined within the distal balloon waist 32. The second series 64 of oblong rectangular formations 60, in contrast, extends through the distal end of the distal balloon waist 32. The two distinct series 62, 64 are spaced so that a portion of the first series 62 overlaps a portion of the
15 second series 64. Because the two series 62, 64 of oblong rectangular formations 60 are staggered, the overlap portion is defined as that area of balloon waist material having more than one series of formations.

Staggering multiple series of formations 60 allows for greater material removal. Additionally, this particular arrangement also provides for increased flow
20 control of molten polymeric material. In particular, the oblong rectangular formations 60 act as a series of channels that may direct and hold flowing polymeric material. Moreover, overlapping staggered formations allows for flowing polymeric material to better cross the series of channels so that the flowing polymeric material is evenly distributed along the entire circumference of the distal balloon waist 32. This added
25 control provides for a more uniform taper 40.

Similar to the previous embodiments depicted in Figures 4 and 5, the oblong rectangular formations 60 may be cut in a manner that entirely removes all material within the confines of their rectangular form. In an alternative embodiment, only a
30 portion of the distal balloon waist 32 material is removed thereby forming a void that reduces the wall thickness of balloon waist 32 within the confines of their form.

Figure 7 shows a fragmented view of yet another distal balloon waist 32 embodiment having balloon waist material removed in a plurality of diamond formations 70. The diamond formations 70 illustrate possible variances in size and

shape of the patterned voids. Similar to the above-described embodiments, varying the size of the diamond formations 70 allows for increased control of flowing molten polymeric material. Larger formations 72 provide for greater polymeric distribution. Initially, these larger formations 72 remove more polymeric material prior to the thermal bonding process. The larger formations 72 additionally provide greater exposed surface area for flowing polymeric material to pool within. Smaller formations 74, in contrast, provide for less pooling. These smaller formations 74 are generally used to direct flowing polymeric material into larger formations 72 and to refine the distal balloon waist into the desirable uniform tapered shape 40. Similar to the previous embodiments discussed herein, the diamond formations 70 may be cut in a manner that entirely removes all material within the confines of their diamond form. In an alternative embodiment, only a portion of the distal balloon waist 32 material is removed thereby forming a void that reduces the wall thickness of balloon waist 32 within the confines of their diamond form.

Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.

WHAT IS CLAIMED IS:

1. A balloon dilatation catheter, comprising:
an elongate shaft having a proximal end and a distal end; and
a balloon connected to the distal end of the shaft, the balloon having an expandable region and a balloon waist, the balloon waist including a plurality of voids prior to thermal reformation that cause the balloon waist to have a reduced profile subsequent to thermal reformation.
2. A balloon dilatation catheter as in claim 1, wherein the balloon waist has a material volume per unit length, and wherein the plurality of voids reduce the material volume per unit length.
3. A balloon dilatation catheter as in claim 2, wherein the material volume per unit length decreases to cause the balloon waist to taper.
4. A balloon dilatation catheter as in claim 1, wherein the size, number and position of the plurality of voids are selected to cause the balloon waist to taper.
5. A balloon dilatation catheter as in claim 1, wherein a proximal balloon waist and a distal balloon waist include a plurality of voids prior to thermal processing that cause the balloon waists to have a reduced profile subsequent to thermal processing.
6. A balloon dilatation catheter as in claim 5, wherein the elongate shaft includes an inner tubular member disposed in an outer tubular member, and wherein the proximal balloon waist is connected to a distal end of the outer tubular member and the distal balloon waist is connected to a distal end of the inner tubular member.
7. A balloon dilatation catheter as in claim 1, wherein the plurality of voids are wedge shaped.
8. A balloon dilatation catheter as in claim 1, wherein the plurality of voids are circular.

9. A balloon dilatation catheter as in claim 1, wherein the plurality of voids are rectangular.

10. A balloon dilatation catheter as in claim 1, wherein the plurality of voids are diamond shaped.

11. A balloon dilation catheter, comprising:
an elongate shaft having a proximal and a distal end; and
a molded balloon attached to the distal end of the shaft, the balloon being molded to have an expandable region and a balloon waist, the balloon waist having a material volume per unit length, wherein the material volume per unit length after attachment to the distal end of the elongate shaft is less than the material volume per unit length immediately after molding of the balloon.

12. A balloon dilatation catheter as in claim 11, wherein the material volume per unit length decreases to cause the balloon waist to taper.

13. A balloon dilatation catheter as in claim 11, wherein the material volume per unit length is controlled by the formation of a plurality of voids in the balloon waist.

14. A balloon dilatation catheter as in claim 13, wherein the size, number and position of the plurality of voids are selected to cause the balloon waist to taper.

15. A balloon dilatation catheter as in claim 13, wherein the plurality of voids are wedge shaped.

16. A balloon dilatation catheter as in claim 13, wherein the plurality of voids are circular.

17. A balloon dilatation catheter as in claim 13, wherein the plurality of voids are rectangular.

18. A balloon dilatation catheter as in claim 13, wherein the plurality of voids are diamond shaped.

19. A method of manufacturing a balloon catheter comprising the steps of:
providing a catheter shaft having a proximal end and a distal end;
providing an expandable balloon having a waist and an expandable portion;
forming a plurality of voids in the balloon waist;
thermally reforming the waist to close the voids and to reduce the profile of the waist; and
attaching the waist to the distal end of the catheter shaft.

20. A method of manufacturing a balloon catheter as in claim 19, wherein the step of attaching the waist comprises a thermal bonding process.

21. A method of manufacturing a balloon catheter as in claim 20, wherein the steps of thermally reforming the waist and attaching the waist are performed simultaneously.

22. A method of manufacturing a balloon catheter as in claim 19, wherein the balloon waist comprises a polymer which melts and flows into the plurality of voids during the step of thermal reforming.

Fig. 1

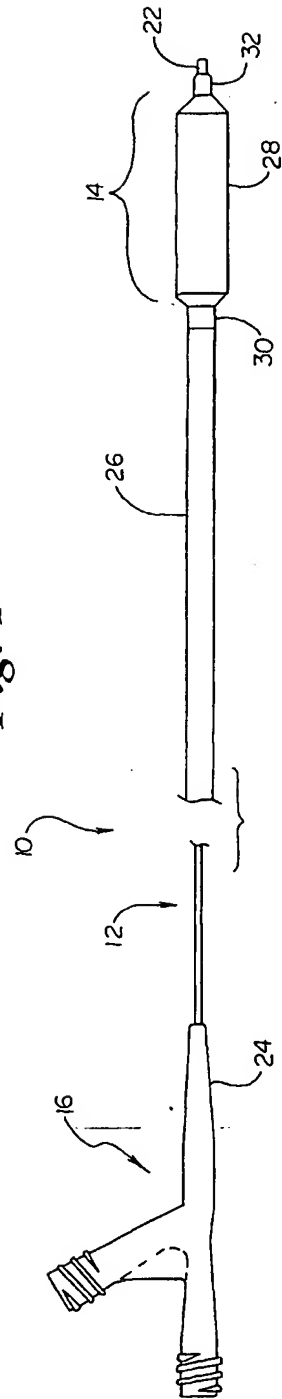


Fig. 3

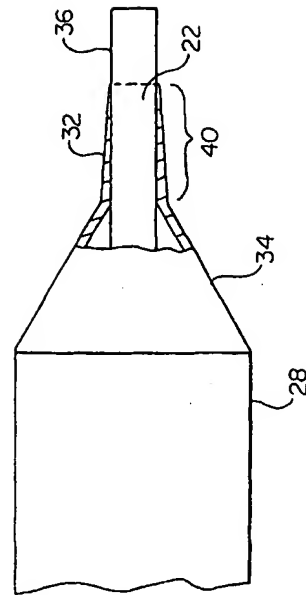


Fig. 2

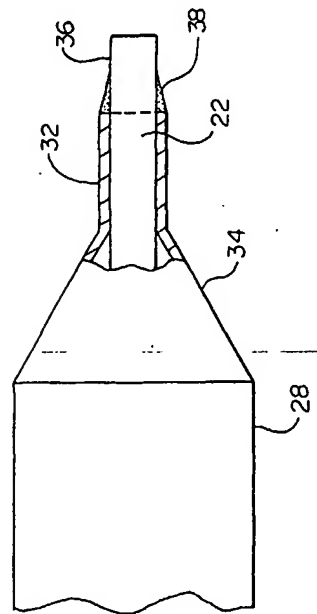


Fig. 4

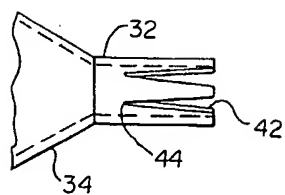


Fig. 5

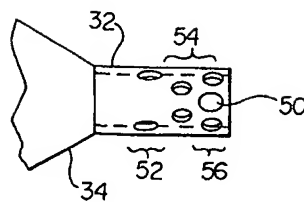


Fig. 6

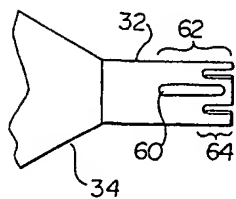


Fig. 7

